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PATENT

Attorney Docket No.: A-70245-2

Attorney File No.: 468899-00040

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BROWN

Serial No. 10/631,106

Filing Date: July 31, 2003

For: *Naphthalimide Compositions and
Uses Thereof*

Examiner: To Be Assigned

Group Art Unit: 1614

CERTIFICATE OF MAILING

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Kent Yonehara

**INFORMATION DISCLOSURE STATEMENT
AND
STATEMENT OF RELATEDNESS**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1273 Off. Gaz. Pat. Off. 1, 8/5/2003, no copies of U.S. patents and U.S. published applications are enclosed.

Further, this application is a divisional of the following related U.S. Application – Serial No. 09/834,177, filed April 12, 2001 (now Patent No. 6,630,173 B1, issued October 7, 2003), and a continuation-in-part of the following related U.S. Application – Serial No. 09/810,527, filed March 15, 2001 (pending). Applicant wishes to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying substitute for form PTO-1449 marked with an asterisk (*). Since these references were previously disclosed in the above-

Serial No.: 10/631,106
Filing Date: July 31, 2003

mentioned applications, in accordance with 37 C.F.R. § 1.98(d), no copies of these references are enclosed.

Further, in satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and as required by M.P.E.P. § 2001.06(b), Applicant notes that the present application is related to the following pending patent applications:

1. U.S.S.N. 10/769,638, filed January 30, 2004, which is a divisional of US Patent No. 6,734,178 (cite A2 on attached form PTO/SB/8A);
2. U.S.S.N. 10/273,801 (a continuation-in-part of U.S.S.N. 09/834,077, filed April 12, 2001, now U.S. Patent No. 6,630,173);
3. U.S.S.N. 09/996,354, filed October 31, 2001 (Publication No. 2002/0123469);
and
4. U.S.S.N. 10/616,178, filed July 8, 2003 (Publication No. 2004/0082788).

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required.

Serial No.: 10/631,106
Filing Date: July 31, 2003

While no further fee is believed to be due, if this belief is in error, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 468899-00040 (A-70245-2/RFT/THR)).

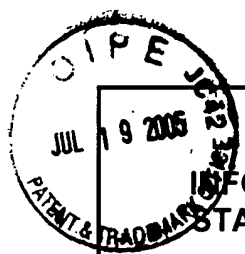
Respectfully submitted,

DORSEY & WHITNEY LLP

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Attachments: Form PTO-SB/8A/B, Substitute for Form PTO-1449
2 cited references
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Substitute for form 1449A/PTO (Modified)			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/631,106	
			Filing Date	July 31, 2003	
			First Named Inventor	BROWN, Dennis M.	
			Art Unit	1614	
			Examiner Name	To Be Assigned	
Sheet	1	of	2	Attorney Docket Number	A-70245-2/RFT/THR (468899-00040)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1 *	5,420,137	05-30-1995	Brana et al.	
	A2	6,734,178 B2	05-11-2004	Brown	
	A3	2003/0176496 A1	09-18-2003	Medford et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B1 *	FR 2 673 944 A1	09-18-1992	Elf Sanofi		
	B2 *	WO 01/68098 A2	09-20-2001	ChemGenex Therapeutics, Inc.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C1 *	ABBOTT, B.J., et al., "Screening Data from the Cancer Chemotherapy National Service Center Screening Laboratories. XXXVI. Plant Extracts," <i>Cancer Res. Supp.</i> , 26(9):1131-1136 (Sep. 1966).	
	C2 *	AJANI, J.A., et al., "In vitro activity of amonafide against primary human tumors compared with the activity of standard agents," <i>Invest. New Drugs</i> , 6(2):79-85 (Jun. 1988).	
	C3 *	ASBURY, R.F., et al., "A Gynecological Oncology Group phase II study of amonafide (NSC #308847) in squamous cell carcinoma of the cervix," <i>Am. J. Clin. Oncol.</i> , 17(2):125-128 (Apr. 1994).	
	C4 *	BERNGES, F., et al., "Combination effects of poly(ADP-ribose) polymerase inhibitors and DNA-damaging agents in ovarian tumor cell lines - with special reference to cisplatin," <i>J. Cancer Res. Clin. Oncol.</i> , 122(11):665-670 (1996).	
	C5 *	COBB, P.W., et al., "Activity of DMP 840, a new bis-naphthalimide, on primary human tumor colony-forming units," <i>J. Natl Cancer Inst.</i> , 86(19):1462-1465 (Oct. 1994).	
	C6 *	COSTANZA, M.E., et al., "Amonafide: An Active Agent in the Treatment of Previously Untreated Advanced Breast Cancer - A Cancer and Leukemia Group B Study (CALGB 8642)," <i>Clin. Cancer Res.</i> 1(7):699-704 (Jul. 1995).	
	C7 *	COSTANZA, M.E., et al., "Safety and efficacy of using a single agent or a phase II agent before instituting standard combination chemotherapy in previously untreated metastatic breast cancer patients: report of a randomized study - Cancer and Leukemia Group B 8642," <i>J. Clin. Oncol.</i> , 17(5):1397-1406 (May 1999).	
	C8 *	EVANS, W.K., et al., "Phase II study of amonafide: results of treatment and lessons learned from the study of an investigational agent in previously untreated patients with extensive small-cell lung cancer," <i>J. Clin. Oncol.</i> , 8(3):390-395 (Mar. 1990).	
	C9 *	GALLION, H.H., et al., "Phase II trial of amonafide in previously treated patients with advanced ovarian cancer: a Southwest Oncology Group study," <i>Gynecol. Oncol.</i> , 46(2):230-232 (Aug. 1992).	
	C10 *	GÜNTHER, A., et al., "Differential Expression of Intermediate-Filament Proteins in Murine Sarcoma 180 Ascites or Solid Tumor," <i>Cancer Res.</i> , 44(6):2590-2594 (Jun. 1984).	
	C11 *	HAYES, D.F., et al., "Treatment of metastatic breast cancer: present and future prospects," <i>Semin. Oncol.</i> , 22(2 Supp. 5):5-19; disc. 19-21 (Apr. 1995).	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/631,106	
			Filing Date	July 31, 2003	
			First Named Inventor	BROWN, Dennis M.	
			Art Unit	1614	
			Examiner Name	To Be Assigned	
Sheet	2	of	2	Attorney Docket Number	A-70245-2/RFT/THR (468899-00040)

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	C12 *	INNOCENTI, F., "Pharmacogenetics: a tool for individualizing antineoplastic therapy," <i>Clin. Pharmacokinet.</i> , 39(5):315-325 (Nov. 2000).		
	C13 *	JIN, X., et al., "Cisplatin combination therapy of murine S180," <i>Shanghai Yike Daxue Xuebao</i> , 16(1):50-54 (1989), Caplus Accession No. 1989:225174, (Abstract only).		
	C14 *	LASTER, W.R., et al., "Therapeutic synergism (TS) of homoharringtonine (H) plus 5-fluorouracil (FU) against leukemia P388 (P388/0) and ARA-C-resistant P388 (P388/ARA-C)," <i>Proc. Am. Assn. Cancer Res.</i> , 23:786 (1982), Embase Accession No. 82182588, (Abstract only).		
	C15 *	MAGNUSSON, K., et al., "Is conversion of solid into more anoxic ascites tumors associated with p53 inactivation?," <i>Oncogene</i> , 17(5):2333-2337 (Nov. 1998).		
	C16	MALONNE, H., et al., "DNA topoisomerase targeting drugs: Mechanisms of action and perspectives," <i>Anti-Cancer Drugs</i> , 8(9):811-822 (1997) (Abstract only).		
	C17 *	PÉREZ, J.M., et al., "Combined effect of platination and intercalation upon DNA binding of novel cytotoxic Pt-bis(naphthalimide) complexes," <i>J. Med. Chem.</i> , 42(26):5482-5486 (Dec. 1999).		
	C18	POWELL, R.G., "Antitumor alkaloids for <i>Cephalotaxus harringtonia</i> : structure and activity," <i>J. Pharm. Sci.</i> 61(8):1227-1230 (Aug. 1972).		
	C19 *	PROVENCHER, D., et al., "Discordance in p53 Mutations When Comparing Ascites and Solid Tumors from Patients with Serous Ovarian Cancer," <i>Tumor Biol.</i> , 18(3):167-174 (1997).		
	C20 *	SAVAGE, K.E., et al., "Effect of tunicamycin, an inhibitor of protein glycosylation, on division of tumour cells <i>in vitro</i> ," 64:295-306 (Nov. 1983).		
	C21 *	TAKANO, I., et al., "Ester-type cephalotaxus alkaloids from <i>Cephalotaxus harringtonia</i> var. <i>drupacea</i> ," <i>Phytochemistry</i> , 44(4):735-738 (1997).		
	C22 *	TAKANO, I., et al., "New Oxygenated <i>Cephalotaxus</i> Alkaloids from <i>Cephalotaxus harringtonia</i> var. <i>drupacea</i> ," <i>J. Nat. Prod.</i> , 59(12):1192-1195 (Dec. 1996).		
	C23 *	VISANI, G., et al., "Effects of homoharringtonine alone and in combination with alpha interferon and cytosine arabinoside on <i>in vitro</i> growth and induction of apoptosis in chronic myeloid leukemia and normal hematopoietic progenitors," <i>Leukemia</i> , 11:624-628 (May 1997).		
	C24 *	WONG, K., et al., "Management of metastatic breast cancer," <i>World J. Surg.</i> , 18(1):98-111 (Jan.-Feb. 1994).		
	C25 *	YUZHU, Z., et al., "Homoharringtonine, cytarabine and aclarubicin (HAA) combination chemotherapy for acute myeloid leukemia (AML)," <i>Chin. J. Clin. Oncol.</i> , 25(10):758-759 (1998), Embase Accession No. 1998384948, (Abstract only).		
	C26 *	ZHANG, S.D., et al., "Inhibitory effects of homoharringtonine and hydroxycamptothecin in combination with other agents on cancer cell growth," <i>Asia Pac. J. Pharmacol.</i> , 7:191-195 (1992).		

Examiner Signature	Date Considered
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